

### **REMARKS**

Claims 1 to 16, 28 to 36, 61, and 62 were pending, and claims 1 to 15, 36, 61, and 62 have been withdrawn from consideration. Claims 16 and 28 to 35 were under examination. Claims 16, 28, and 62 have been amended. Claims 63 and 64 have been added. No new matter has been added. Claims 16, 28 to 35, 63 and 64 will be under examination after entry of the present amendment.

The Examiner has rejected claims 16 and 28 to 35 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular the Examiner states that in claims 16 and 28, the disclosure does not describe “the material removing element *being positioned beneath the cage*”. In response thereto Applicant has amended claims 16 and 28 to cancel the wording objected to by the Examiner. As amended claims 16 and 28 each recite that the cage has an inner surface that “defines a cavity” and that the material removing element is positioned “within the cavity”. This feature is clearly shown in the drawings and is consistent with the description of the device in the specification. Therefore, Applicant requests that this ground of rejection be withdrawn.

The Examiner has rejected claims 16, 28 to 30 and 33 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,245,012 to Kleshinski. Applicant respectfully traverses this rejection of the claims. However, in order to expedite prosecution claims 16 and 28 have been amended. Claims 16 and 28 are the only independent claims under examination. Each is directed to a device for removing material from a vessel wall at a vascular site. The device includes a cage and a material removing element. The cage has a plurality of openings and an inner surface which defines a cavity. The cage is moveable from a collapsed position to an expanded position. The cage is configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings. The material removing element is

positioned within the cavity and is configured to be moveable along the inner surface of the cage to remove material from the vessel wall which extends through the openings.

The Examiner states that Kleshinski discloses in FIGS. 1 and 3 a device for removing material from a vascular site having the limitations recited in claims 16 and 28. Specifically, the Examiner states that the device includes a cage (10 or 40) that has a plurality of openings (at 18) formed by rigidly connected elements (16) and an inner surface. The Examiner states the device includes a material removing element (14) positioned within the cage that is capable of removing the material extending into the openings, and that the material removing element is inherently movable along the inner surface of the cage to remove the material extending into the openings. The Examiner acknowledges that Kleshinski is silent regarding the material removing element being positioned beneath the cage. However, the Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made “to reverse the position of stent 14 of being positioned beneath the cage, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art”.

Applicant admits to some confusion regarding the Examiner’s interpretation of the device disclosed by Kleshinski. The Examiner identifies elements 10 or 40 as the “cage”. These elements are described by Kleshinski as being the free standing filters shown in FIGS. 1 and 3 (and 2). Those filters include a frame and a filter mesh. For example, the frame of filter 10 is identified as stent 14 and the filter mesh is identified as filter material 22. The frame extends over the filter mesh (Col. 4, Line 11; and FIG. 2). However, the Examiner identifies the stent 14 as comprising the material removing element. Therefore, it is not clear to Applicant which portion of the Kleshinski device the Examiner considers to comprise the cage or the inner surface of the cage. Presumably the “cage” is the filter mesh material 22 and the “inner surface” is the inner surface of the filter mesh material 22

since the mesh material is surrounded by the stent and since the stent has been identified by the Examiner as comprising the “material removing element”. If that assumption is correct then the Examiner’s conclusion that the “material removing element is inherently movable along the inner surface of the cage” is incorrect for at least several reasons. First, the stent 14 in Kleshinski is not positioned on the inner surface of the filter mesh material. Rather it extends over that material. In order for a reference to inherently disclose a feature that feature must necessarily be present in the reference. It is not enough that the feature might possibly be present. Here the feature is clearly not present since the stent is positioned exterior to the mesh material or along the outer surface of the mesh material and, therefore, can not be moveable over the inner surface of the mesh material. Second, even if the Examiner is correct in asserting that it would be obvious to reverse the position of the stent 14 such a modification would not result in a device which inherently has the features of claims 16 and 28. Specifically, even if the stent 14 was positioned within the mesh material the stent 14 would not be inherently or necessarily movable along the inner surface of the filter mesh. This is especially so given the fact that Kleshinski describes the stent as being “attached” to the filter material (Col. 4, Lines 8 to 10). Such attachment would clearly work to prevent movement of the stent with respect to the inner surface of the mesh material. Therefore, Applicant asserts that stent 14 is not configured to be moveable along the inner surface of a cage or even capable of moving along the inner surface of any structure that could comprise the cage including the mesh material 22.

The Examiner’s interpretation of Kleshinski is also confusing with respect to the description of the “openings”. Claims 16 and 28 recite that the cage has a plurality of openings. The Examiner identifies the openings as occurring at 18 and being formed by elements 16. However, Kleshinski describes elements 16 as being “elongate lead wires 16 which extend between an open proximal end 18 of the stent and a spaced coupling 20”

(Col. 4, Lines 4 to 7). As interpreted by the Examiner the wires 16 must be part of the cage since they define the openings in the cage. Clearly, as described by Kleshinski and as shown in the drawings the stent 14 is distal to the wires 16 and is not configured to be moveable along the inner surface of the wires.

Applicant further submits that no matter how the device disclosed in Kleshinski is interpreted, that device does not include structure that explicitly or inherently comprises a cage having an expanded position configured such that when in the expanded position at the vascular site material from the vessel wall at the vascular site extends into openings in the cage and that comprises a material removing element configured to be moveable along the inner surface of the cage to remove the material extending from the vessel wall into the openings.

Further, a person of skill in the art at the time of the invention would have no reason to modify Kleshinski in the manner required by claims 16 and 28. Kleshinski is concerned with providing a free standing filter that overcomes the stated disadvantages of prior art filters which are attached to a guidewire or catheter. The filters described in Kleshinski are designed to be used in cooperation with other devices such as balloon angioplasty catheters. Those other devices are used to treat vessel stenosis or occlusion. During use of these devices plaque and emboli might be dislodged from the treatment site. Kleshinski's filters are meant to capture any such plaque or emboli which may result from use of those treatment devices. A person of skill in the art would be expected to use Kleshinski's filters in combination with other treatment devices. Therefore, the person of skill in the art would have no reason to modify those filters so that the filters themselves could be used to remove material from a vessel wall as recited in claims 16 and 28. Specifically, a person of skill in the art would not modify the filters to include a cage having an expanded position configured such that when in the expanded position at the vascular site material from the vessel wall at the vascular site extends into openings in the

cage and to further include a material removing element configured to be moveable along the inner surface of the cage to remove the material extending from the vessel wall into the openings.

For at least the reasons set forth above claims 16 and 28 are allowable over Kleshinski. Claims 29, 30 and 33 depend from claim 28 and add further significant limitations which distinguish over Kleshinski and are allowable for at least the same reasons as claim 28.

The Examiner has rejected claims 31 and 32 under 35 U.S.C. § 103(a) as being unpatentable over Kleshinski in view of U.S. Patent No. 5,100,423 to Fearnot. Applicant traverses this rejection. Claims 31 and 32 depend from claim 28 and are allowable for at least the same reasons as claim 28. Further, claims 31 and 32 additionally recite a collapsible bag positioned to receive material removed by the material removing element. The Examiner acknowledges that Kleshinski does not teach such a bag but asserts that such a bag or net is taught by Fearnot. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify Kleshinski by adding the bag or net taught by Fearnot. Applicant disagrees. A person of skill in the art would recognize that the filter disclosed by Kleshinski includes both a frame and a fine mesh filter material. Applicant respectfully submits that a person of skill in the art would have no reason to further modify Kleshinski to add the bag or net of Fearnot since the same or similar function is already provided by the fine mesh filter material already present in the filter device. As a matter of fact Applicant submits that a person of skill in the art would avoid such a modification since the addition of additional structure in the form of the bag or net would unnecessarily increase the bulk and crossing profile of the distal end of the device. Therefore, claims 31 and 32 are allowable for at least these reasons.

The Examiner has rejected claims 34 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Kleshinski. Applicant traverses this rejection. Claims 34 and 35 depend from claim 28 and are allowable for at least the same reasons as claim 28.

Newly presented claims 63 and 64 depend from claim 16 and are allowable for at least the same reasons as claim 16. Further, claims 63 and 64 additionally recite a collapsible bag positioned to receive material removed by the material removing element and are substantially similar to claims 31 and 32. Therefore, claims 63 and 64 are also allowable for at least the same reasons set forth above with respect to claims 31 and 32.

In view of the foregoing Applicant submits that all of the pending claims are allowable and requests that the rejections be withdrawn.

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Respectfully submitted,

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